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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,233	12/12/2001	Jamey D. Marth	19452A-000130US	9630

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EXAMINER

NOLAN, PATRICK J

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,233

Applicant(s)

MARTH ET AL.

Examiner

Patrick J. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-37 is/are pending in the application.
- 4a) Of the above claim(s) 27-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-21-05</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 26-37 are pending. Claims 1-25 and 38-51 have been cancelled.
2. Applicant is requested to amend the first line of the specification with the 35 USC § 371 data.
3. During a telephonic conversation with Kevin Bastian, Applicant's representative indicated the Examiner had examined the wrong Group. Group XVI, claims 26-29 was examined instead of Group XIX, claims 26 and 35-37. The Examiner thought the Applicant had requested the change, but since he had no evidence of such a request, i.e. an Interview Summary, the written record clearly indicated Group XIX, claims 26 and 35-37 was to be examined and so a new Non-Final Office Action is set forth below. The Examiner apologizes for the delay in prosecution.
4. Claims 27-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8-5-04.
5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 26 and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
The recitation of either or both in base claim 26, line 6 is confusing because either the glycoprotein marker is present or absent and said change is indicative of a disease state, not both at the same time.
The recitation of antibodies B220 and 1B11 in claim 37 is indefinite because these are laboratory designations that can change over time. Insertion of an accepted depository accession number for each antibody would overcome this rejection.

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The recitation of “reduced binding to a detection agent which specifically binds to a Core 2 type O-glycans” is indefinite because the base claim 26 from which it ultimately depends requires either the oligosaccharide to be present or absent and if so the disease is present. The ability of the glycoconjugate to have reduced binding with the detection reagent is in direct contrast from claim 26, which requires an all or nothing detection system.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 26 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting C2 GlcNAc transferase deficiency by detecting decreased Core 2 type glycans on neutrophils, does not reasonably provide enablement for detecting any genetically transmitted myeloid deficiency by detecting any decrease of any glycoconjugate on myeloid cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Scope of the claims is drawn to detecting any genetically transmitted immune system myeloid deficiency by detecting any glycoconjugate on any myeloid cell. The specification provides no guidance as to what diseases are encompassed by the term genetically transmitted immune system dysfunction caused by myeloid deficiency. In a review of the state of the art, it is unknown to the Examiner of any art recognized genetically transmitted immune system dysfunction caused by myeloid deficiency that is related to glycoconjugate presence or absence. The only working example in the specification demonstrates that mice made deficient in C2 GlcNAc transferase have a defect in the ability of their neutrophils to be recruited to sites of inflammation. However the actual numbers of neutrophils do not decrease, in fact they increase the absence of C2 GlcNAc transferase, so in the full scope of the term myeloid deficiency, the neutrophils are only deficient in function not numbers. Applicant has no working examples

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demonstrating the detecting of any other glycoconjugate on any other myeloid cell in any other disease state.

Since Applicant's specification is limited to detecting a decrease in neutrophil function and not number, the breadth of the term deficiency is not fully enabled. Since they have no working examples demonstrating decreased myeloid numbers in any genetically transmitted immune system dysfunction and their only working examples demonstrates an increase not a decrease in number, but a decrease in function, it would be unpredictable to practice the full scope of the claimed invention without an undue amount of experimentation.

9. Claims 26 and 35-37 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant does not have adequate written description for the term "myeloid deficiency". The scope of the term is potentially very large as any disease that results in immune system dysfunction is genetically transmitted and has a decrease or increase in a glycoconjugate on any myeloid cell is encompassed by the term. In a review of the specification there are no naturally occurring diseases described which are genetically transmitted, involved in immune dysfunction and have a myeloid deficiency as a result of a glycoconjugate increase or decrease. The only description is for a knockout mouse made by the hand of man. Absent this teaching the amount of description is non-existent. The description of one species does not adequately describe the genus term "myeloid deficiency".

10. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

4/15/2005